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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,834

08/08/2006

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023312-0117

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22428 7590 12/30/2008  
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EXAMINER

MCDOWELL, BRIAN E

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

12/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,834	<b>Applicant(s)</b> ISOGAI ET AL.	
	<b>Examiner</b> BRIAN MCDOWELL	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11/12/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,11,13, and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**  
**RESPONSE TO ELECTION/RESTRICTION**

Applicant's election without traverse of group I in the reply filed on 11/12/2008 is acknowledged.

Claims 9,10, and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

This application contains claims drawn to an invention nonelected without traverse in the reply filed on 11/12/2008. A complete reply to this action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

An action on the merits of claims 1-8,11,13, and 14 is contained herein.

***Priority***

This application claims the priority date of 4/21/2003. However, a certified English version of the foreign priority document was not received.

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Thus, the effective filing date of this application is 4/20/2004.

***Information Disclosure Statement***

The information disclosure statement filed 10/20/2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

***Claim Objections***

Claims 13 and 14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. **The for use limitations are not considered and hold no patentable weight.**

***Claim Rejections - 35 USC § 112 (2<sup>nd</sup> Paragraph)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-8, 11, 13, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For example in claim 1, applicant recites the limitation "where Bi represents an optionally substituted biotinyl group". It is unclear what applicant means by the term "optionally substituted". The specification provides a brief list of substituents (e.g., halogens) that may be substituted on the biotinyl group which would not interfere with purification of the hemoprotein, however one of ordinary skill would not know what other moieties would also be encompassed by this limitation; thus the metes and bounds of the claims are unclear. Claims 2-4,6-8,11,13, and 14 depend on claim 1 and therefore are indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

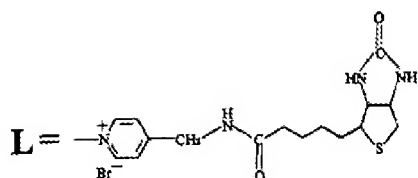
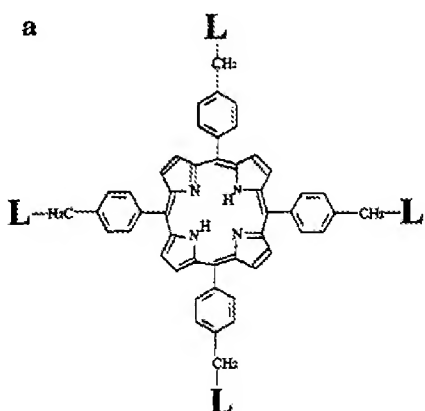
A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated over Fukushima *et al.* (Langmuir)-mentioned in ISR and IDS.

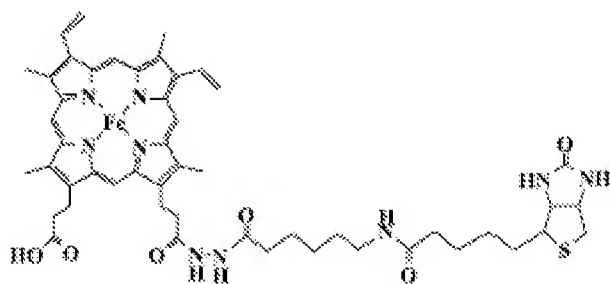
Fukushima *et al.* teach the following compound (see page 3524, compound(a)):



wherein A is a heterohydrocarbyl group which possesses an unsubstituted biotinyl moiety that read on the aforementioned claims and are therefore anticipated.

Claims 1-8,11,13, and 14 are rejected under 35 U.S.C. 102(a) as being anticipated over Ishida *et al.* (Analytical Biochemistry)-mentioned in IDS.

Ishida *et al.* teach the following compound and process of making said compound (see page 139, Figure 1):



wherein A is a heterohydrocarbyl group which possesses an unsubstituted biotinyl moiety that read on the aforementioned claims and are therefore anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8,11,13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida *et al.* (Analytical Biochemistry)-mentioned in IDS in view of Roelant *et al.* (US Patent 5,998,128)-mentioned in ISR.

Ishida *et al.* taught what was stated previously.

This document does not disclose other heme-like porphyrins (e.g., heme a, heme c, etc.) that are attached to a biotinyl group.

Roelant *et al.* disclose several heme-like porphyrins (including the instantly claimed heme-b). Furthermore, this document discloses that the aforementioned porphyrins can be linked to certain moieties such as biotin and avidin and consequently be used in processes for labeling, detecting, and quantifying chemical/biological entities (see abstract and col.2, lines 12-14).

In summary, it would have been *prima facie* obvious for one of ordinary skill in the art to take a porphyrin such as heme b or a similar derivative thereof (e.g., heme a, heme c, etc.) and link said porphyrin to a biotinyl group using a similar process



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described by Ishidia, and consequently use this compound in one of the processes described above. Therefore, the claims are obvious.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

**/James O. Wilson/**

**Supervisory Patent Examiner, Art Unit 1624**